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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,473	11/08/2001	Michael Hagen	33,482-00	3152

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,473	HAGEN, MICHAEL	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *11/08/01,07/16/05,10/11/04 and 01/28/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *88-185* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *88-93,96-98,105,109,116-122,125,126,160,161,163-165 and 167* is/are rejected.

7)☒ Claim(s) *89, 105, 109, 117, 160-161, 163-165 and 167* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

JC

Continuation of Disposition of Claims: Claims withdrawn from consideration are 94,95,99-104,106-108,110-115,123,124,127-159,162,166 and 168-185.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 88-104, SEQ ID NO: 2, and granulocyte macrophage colony stimulating factor, in the reply filed on 10/21/04 and 01/28/05 is acknowledged.

Additionally, as stated to Applicant earlier, the elected composition will also be examined with its corresponding method of use, "method for increasing the ability of an antigenic composition comprising administering the composition".

Status of claims

2. Claims 88-185 are pending. Claims 94-95, 99-104, 106-108, 110-115, 123-124, 127-159, 162, 166 and 168-185 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/21/2004 and 01/28/05. Claims 88-93, 96-98, 105, 109, 116-122, 125-126, 160-161, 163-165 and 167 are under examination.

Claim Objections

3. Claims 89, 105, 109, 117, 160-161, 163-165 and 167 are objected to because of the following informalities:

Regarding claims 89 and 117, the claims are objected to because of the presence of repetitive language in the claims, e.g., polypeptide, peptide, and protein.

Regarding claims 105, 109, 160-161, 163-165 and 167: the claims are directed to a method of increasing the ability of an antigenic composition containing an HIV antigen to do perform an immune stimulating task in a vertebrate host by administering to said host

the antigenic composition. However, currently as written, the claims do not require the elicitation of an immune response against the pathogen of interest in a host.

Regarding claims 109, 164-165 and 167, the claims are objected to because the recitation "elicit cytotoxic T lymphocytes in a vertebrate" appears to be incomplete. The Examiner suggests amending the recitation to indicate that it is the elicitation of cytotoxic T lymphocyte response that is desired.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 98, 105, 109,116-122, 125-126, 160-161, 163-165 and 167 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding the above listed claims, the phrase "derived from" renders the claim(s) indefinite because one skilled in the art would not be able to reasonably ascertain the scope of the cited limitation.

Regarding claims 105 and 109, the claims are also indefinite because of the recitation "selected antigen". It is unclear what is encompassed by "selected".

Regarding claims 105, 109, 160-161, 163-165 and 167, the claims are rendered indefinite because it is unclear how the administration of the claimed antigenic composition would result in an increase in the ability of the antigenic composition to elicit an immune response, including cytotoxic T lymphocyte response, in a host.

the antigenic composition. However, currently as written, the claims do not require the elicitation of an immune response against the pathogen of interest in a host.

Regarding claims 109, 164-165 and 167, the claims are objected to because the recitation "elicit cytotoxic T lymphocytes in a vertebrate" appears to be incomplete. The Examiner suggests amending the recitation to indicate that it is the elicitation of cytotoxic T lymphocyte response that is desired.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 98, 105, 109,116-122, 125-126, 160-161, 163-165 and 167 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding the above listed claims, the phrase "derived from" renders the claim(s) indefinite because one skilled in the art would not be able to reasonably ascertain the scope of the cited limitation.

Regarding claims 105 and 109, the claims are also indefinite because of the recitation "selected antigen". It is unclear what is encompassed by "selected".

Regarding claims 105, 109, 160-161, 163-165 and 167, the claims are rendered indefinite because it is unclear how the administration of the claimed antigenic composition would result in an increase in the ability of the antigenic composition to elicit an immune response, including cytotoxic T lymphocyte response, in a host.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 88-90 and 96-97 are rejected under 35 U.S.C. 102(a) as being anticipated by Boon et al., WO 9857659.

The claims are directed to an antigenic composition comprising an antigen and an effective amount of the combination of 3-O-deacylated monophosphoryl lipid A and a cytokine. The claims require 3-O-deacylated monophosphoryl lipid A be used in a form of a stable oil in water emulsion, the claimed composition to comprise a diluent or carrier, and that the antigen is a peptide.

Boon et al. teaches to an antigenic composition comprising an antigen and an effective amount of the combination of 3-O-deacylated monophosphoryl lipid A and a cytokine. The antigen Boon et al. teaches is a peptide. Boon et al. also teaches the use of 3-O-deacylated monophosphoryl lipid A in a form of a stable oil in water emulsion. The antigenic composition of Boon et al. is also comprises a diluent or carrier. Boon et al. teaches the claimed antigenic composition. Ergo, Boon et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 98, 116-117, 119 and 125-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon et al., WO 9857659, as applied to claims 88, 90 and 96-97 above.

Claim 98 requires that the antigen be derived from a pathogenic virus. Claims 116-117 further limits the pathogenic virus to HIV protein. Claim 119 requires the 3D-MPL present in claim 98 be used in the form of a stable oil-in-water emulsion. Claim 125 requires that the composition of claim 98 to comprise a diluent or carrier. Claim requires the 3D-MPL present in claim 125 be used in the form of a stable oil-in-water emulsion.

The relevance of Boon et al. is provided above.

The antigenic composition of Boon et al. does not contain an antigen that is derived from a pathogenic virus, particularly HIV. However, Boon et al. suggests the use of other antigens, including HIV proteins. [Lines 20-31 of page 4.] Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use other art-recognized antigen in the antigenic composition. One of ordinary skill in the at the time the invention was made would have been motivated to use HIV proteins as the antigen to produce a composition for use in HIV treatment. One of ordinary skill in the art would have had a reasonable expectation of success for doing so because the art recognizes the suitability of HIV proteins as antigens. Ergo, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

10. Claims 105, 109, 160-161, 163-165 and 167 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon et al., WO 9857659, as applied to claims 88, 98, 116 and 125-126 above.

Claims 105, 160-161 and 163 require the administration of the composition of claims 98, 116 and 125-126, respectively, to a vertebrate host to elicit an immune response in said host.

Claims 109, 164-165 and 167 require the administration of the composition of claims 98, 116 and 125-126 to a vertebrate host to elicit cytotoxic T lymphocyte response in said host.

The relevance of Boon et al. is provided above.

Boon et al. does not teach the administration of the composition of claims 98, 116 and 125-126 to a vertebrate host to elicit an immune response in said host. However, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer the antigenic composition of claims 98, 116 and 125-126 to a host. One of ordinary skill in the art at the time the invention was made would have been motivated to administer said antigenic composition to a vertebrate host to elicit an immune response in the host, including cytotoxic T lymphocyte response. One of ordinary skill in the art at the time the invention was made would have had reasonable expectation of success because Boon et al. teaches the administration of antigenic compositions to elicit cytotoxic T lymphocyte response. [Lines 10-14 of page 3 teaches the use of cytokine, IL-12 to induce cytotoxic T lymphocyte generation, and lines 10-30 of page 7 teaches the administration of the antigenic composition comprising IL-12.] Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a

reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

11. Claim 118 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boon et al., WO 9857659 in view of Haynes et al., U.S Patent No. 5993819, as applied to claims 88, 98 and 116-117 above.

The claim requires the antigen to one having SEQ ID NO: 2.

The relevance of Boon et al. is provided above.

Boon et al. does not teach SEQ ID NO: 2. However, Boon et al. suggest the use of HIV proteins the adjuvant formulation.

Haynes et al. teaches an antigen having a sequence of 100% identity to that of claimed SEQ ID NO: 2, as evidenced by result no. 1 of rag sequence result summary.

Thus, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use an art recognized antigen in place of another. One of ordinary skill in the art at the time the invention was made would have been motivated to use the antigen of Haynes with the adjuvant formulation of Boon et al. to make an antigenic composition for use in HIV treatment. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for making the claimed antigen composition because Haynes et al. teaches an antigen and Boon et al. teaches the use of an antigen with an adjuvant formulation. Ergo, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

11. Claim 118 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boon et al., WO 9857659 in view of Haynes et al., U.S Patent No. 5993819, as applied to claims 88, 98 and 116-117 above.

The claim requires the antigen to one having SEQ ID NO: 2.

The relevance of Boon et al. is provided above.

Boon et al. does not teach SEQ ID NO: 2. However, Boon et al. suggest the use of HIV proteins the adjuvant formulation.

Haynes et al. teaches an antigen having a sequence of 100% identity to that of claimed SEQ ID NO: 2, as evidenced by result no. 1 of rag sequence result summary.

Thus, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use an art recognized antigen in place of another. One of ordinary skill in the art at the time the invention was made would have been motivated to use the antigen of Haynes with the adjuvant formulation of Boon et al. to make an antigenic composition for use in HIV treatment. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for making the claimed antigen composition because Haynes et al. teaches an antigen and Boon et al. teaches the use of an antigen with an adjuvant formulation. Ergo, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

12. Claims 91-93 and 120-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon et al., WO 9857659, as applied to claims 88, 90, 98 and 116 above, in further view of Whittle et al., U.S Patent No. 5955087.

The claims limit the cytokine to granulocyte macrophage colony stimulating factor.

Boon et al. does not teach granulocyte macrophage colony stimulating factor. Boon et al. only teaches the use of IL-12, a cytokine. Whittle et al. teaches the use of granulocyte macrophage colony stimulating factor and IL-12 as an immunostimulatory molecules. [Lines 10-47 of column 7.] Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use one art recognized immunostimulatory molecule in place of another. One of ordinary skill in the art would have had a reasonable expectation of success for doing so because IL-12 and granulocyte macrophage colony stimulating factor are recognized in the art as immunostimulatory molecules, as noted by Whittle et al. Ergo, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

Conclusion

13. No claim is allowed.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. Glenn et al., U.S. Patent No. 6797276, teaches an antigenic composition comprising an antigen and an effective amount of an adjuvant. [Abstract, lines 08-67 of column 16 to lines 1-59 of column 18, and claim 1.]

b. Reed et al., U.S. Patent No. 6350456, teaches an antigenic composition comprising an antigen and an effective amount of an adjuvant. [Abstract, and lines 40-60 of column 3]

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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